DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
JFK Federal Building, Government Center
Room 2325
Boston, MA 02203

CENTERS FOR MEDICARE & MEDICAID SERVICES

Northeast Division of Survey & Certification

March 26, 2019

Kim Hriceniak
CLIA Laboratory Program
Department of Public Health
410 Capitol Avenue, MS #12 HSR
PO Box 340308
Harford, CT 06134-0308

Dear Ms. Hriceniak:

On January 29, 2019, the Department of Public Health, Connecticut State Agency (SA), completed a complaint survey at Bridgeport Hospital Laboratory, Bridgeport, CT where condition level deficiencies were found under 42 C.F.R. § 493.1219 – Histopathology; § 493.1259 – Laboratory General Supervisor, High Complexity Testing; and § 493.1441 – Laboratory Director, High Complexity Testing, and submitted a CMS-2567 - Statement of Deficiencies to the Centers for Medicare & Medicaid Services (CMS). By letter dated February 5, 2019, CMS imposed sanctions against the laboratory's CLIA certificate on the basis of IJ. On February 20, 2019, CMS notify the Bridgeport Hospital Laboratory that based on a revisit performed on February 11, 2019, that IJ had been removed. However, the laboratory was found to still be out of compliance with condition-level, and proposed sanctions against the laboratory's CLIA certificate. The laboratory was provided with an opportunity to respond to the sanction actions and was given appeal rights.

On February 27, 2019, CMS received the laboratory's submission of an allegation of compliance (AOC) and evidence of correction. After being reviewed the AOC was found to be credible and the evidence of correction acceptable. On March 20, 2019, the CMS RO notified the Bridgeport Hospital Laboratory that the submission was credible and acceptable. We are now requesting that the SA perform an on-site revisit at this laboratory to review compliance with all deficiencies cited and the ability to perform tests under the limited subspecialty of Pathology: Histopathology. This follow-up is to be conducted no later than April 5, 2019. The SA is to notify CMS of its findings using form CMS-2567B by April 10, 2019.

The laboratory continues to be accredited by its accreditation organization and retains its CLIA certificate of accreditation during this monitoring period. The laboratory, however, becomes subject to the same requirements and survey and enforcement procedures applied to non-accredited laboratories found out of compliance following a survey. The laboratory is monitored until it reaches Condition-level compliance or its certificate of accreditation is revoked.

If you have any questions, please contact Dina Caloggero at (617) 565-1286 or via email: (dina.caloggero@cms.hhs.gov) or Bethzaida Rodriguez at (617) 565-2146 or via email: (Bethzaida.Rodriguez@cms.hhs.gov).

Sincerely,

Daniel M. Kristola
Branch Manager
Certification and Enforcement Branch

Cc: Karen Dyer, CMS, Central Office, Baltimore, M.D.
Amy Daniels, CAP